MEMORANDUM ENDORSEMENT

FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.
17 Civ. 00124 (LLS)

Defendants are granted leave to file their respective Motions for Summary Judgment (see Letter Motions, Dkt. Nos. 195, 196).

So Ordered.

Dated: New York, New York
January 24, 2022

Louis L. Stanton
LOUIS L. STANTON
U.S.D.J.

COZEN O'CONNOR

MEMO ENDORSED

December 15, 2021

VIA ECF

Michael B. de Leeuw
Direct Phone 212-908-1331
Direct Fax 646-461-2090
mdeleeuw@cozen.com

Hon. Louis L. Stanton, U.S.D.J.
United States District Court, S.D.N.Y.
500 Pearl Street
New York, NY 10007

Re: FTC, et al. v. Quincy Bioscience Holding Co., LLC,, et al., 17-cv-00124-LLS

Your Honor:

We submit this letter pursuant to Rule 2(A) of Your Honor's Individual Practices on behalf of Defendant Mark Underwood, to seek the Court's permission to file a Motion for Summary Judgment for lack of personal jurisdiction for the claims asserted by the New York Attorney General ("NYAG").[1] It is critical that the Court address personal jurisdiction prior to upcoming merits determinations on summary judgment or at trial. *Sinochem Int'l. Co. Ltd. v. Malay. Int'l. Shipping Corp.*, 549 U.S. 422, 430-31 (2007) ("a federal court generally may not rule on the merits of a case without first determining that it has jurisdiction ... over the parties (personal jurisdiction).") (quoting *Steel Co. v. Citizens for Better Environment*, 523 U.S. 83 (1998)); *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 584 (1999) ("Personal jurisdiction, too, is 'an essential element of the jurisdiction of a district ... court,' without which the court is 'powerless to proceed to an adjudication.'"); *Mones v. Com. Bank of Kuwait, S.A.K.*, 204 F. App'x 988, 990 (2d Cir. 2006) (declining to rule on merits of case before deciding question of personal jurisdiction).

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Mr. Underwood previously moved to dismiss all claims for lack of personal jurisdiction, arguing that the FTC Act does not confer nationwide jurisdiction and that the plaintiffs could not satisfy New York's long-arm jurisdiction over Mr. Underwood, a non-New York defendant. In its July 24, 2019 Order and Opinion, this Court held that the FTC Act *did* confer nationwide jurisdiction. As to the NYAG's claims, this Court then held that,

> under the doctrine of pendent personal jurisdiction, where a federal statute authorizes nationwide service of process, and the federal and state claims derive from a common nucleus of operative fact, the district court may assert personal jurisdiction over the parties to the related state law claims even if personal jurisdiction is not otherwise available." *IUE AFL-CIO Pension Fund v. Herrmann*, 9 F.3d 1049, 1056 (2d Cir. 1993) (citation and internal quotation marks omitted). Because the federal and state law claims derive from the same facts concerning the alleged false advertising of Prevagen, there is personal jurisdiction over Mr. Underwood [] with respect to both the FTC Act and New York claims.

[1]Mr. Underwood anticipates joining in the arguments contained in the forthcoming pre-motion letter for summary judgment to be filed by the corporate defendants, but in doing so does not waive the personal jurisdiction challenges set forth herein.

(July 24, 2019 Opinion and Order, at p. 14.) Mr. Underwood's proposed motion for summary judgment would challenge, as a legal matter, this finding of "pendent personal jurisdiction" as relied upon by the Court in allowing the NYAG's claims against a non-New York defendant.[2]

The concept of pendent personal jurisdiction from *IUE AFL-CIO* considers the propriety of a court exerting personal jurisdiction over a defendant in a specific scenario: where state law claims by Plaintiff A[3] share a nexus with an "anchor" claim brought by Plaintiff A as to which there is uncontested personal jurisdiction (in that case, because of the federal claim's nationwide service of process provision). In other words, *IUE AFL-CIO* applies only where both the "anchor" claim and the additional claims for which personal jurisdiction is sought are ***brought by the same plaintiff***. This limitation of *IUE AFL-CIO Pension Fund* has been recognized by federal courts in this context. *See, e.g., Canaday v. Anthem Cos., Inc.*, 9 F.4th 392, 401 (6th Cir. 2021) (distinguishing a form of pendent *claim* personal jurisdiction for which *IUE AFL-CIO* lends support from the doctrine of "[p]endant *party* personal jurisdiction [which] recognizes that a court's exercise of personal jurisdiction over one defendant as to a particular claim by one plaintiff allows it to exercise personal jurisdiction with respect to similar claims brought by other plaintiffs"); *In re Bard IVC*, 2016 WL 6393596, at n. 4 (D. Ariz. Oct. 27, 2016) (noting that "[s]ome cases have recognized a form of pendent personal jurisdiction with respect to multiple claims of a single plaintiff," and citing to *IUE AFL-CIO*, but concluding, "[e]ven if this doctrine is viable, it applies to claims asserted *by a single plaintiff*, not claims asserted by different plaintiffs."); *In re: FCA US LLC Monostable Elec. Gearshift Litig.*, 2017 WL 11552971, at *4 (E.D. Mich. Apr. 19, 2017) (citing *IUE AFL-CIO* for the proposition that "The courts of appeals that accept the notion of 'pendent personal jurisdiction' ... reasoned that because the defendant was summoned properly before the court, due process was not offended by exercising personal jurisdiction over the defendant for the purpose of hearing additional, factually intertwined claims brought in the same case, *by the same plaintiffs*, without regard to whether personal jurisdiction separately could be obtained over those claims alone") (emphasis in original).

But that is not the situation here where the "anchor" claim that would serve as the predicate for personal jurisdiction over Mr. Underwood is one brought by the FTC, but it is the NYAG—*a different plaintiff*—that is seeing to use the "anchor" claim to gain personal jurisdiction over Mr. Underwood. Allowing a plaintiff to piggyback on the personal jurisdiction of a claim brought by a *different* plaintiff, even if the claims of the two plaintiffs overlap, is an impermissibly broad extension of the doctrine of pendent personal jurisdiction that has been routinely rejected by federal courts nationwide.[4] *See, e.g., Story v. Heartland Payment Sys., LLC*, 461 F. Supp. 3d 1216, 1230 (M.D. Fla. 2020) (noting plaintiffs propose "expand[ing] the doctrine [of pendent personal jurisdiction] to include additional pendent party plaintiffs, not just pendent claims," and noting that there was no 11th Circuit authority "adopting this theory"); *Wiggins v. Bank of Am., N.A.*, 488 F. Supp. 3d 611, 624 (S.D. Ohio 2020) ("pendent personal jurisdiction is most frequently applied when the Court has personal jurisdiction over 'some, but not all, of a *plaintiff's* related claims," and noting "[t]his court has previously declined to exercise its discretion to apply pendent jurisdiction when *multiple plaintiffs*—not a single plaintiff—assert separate claims against the same defendants [because] this application of pendent jurisdiction raised serious Due Process Clause concerns" and "the Court cannot offend Due Process Clause in order to create efficiency")

[2] Mr. Underwood continues to disagree with, and wishes to preserve for appeal, the Court's finding that the FTC Act confers nationwide jurisdiction and, for purposes of this pre-motion letter only and without waiver of the ability to challenge that finding, accepts the premise that there is jurisdiction as to Mr. Underwood for the FTC Act claims.
[3] In *IUE AFL-CIO*, it was a set of plaintiffs that made the same federal and additional state claims.
[4] These rulings are consistent with the caution that "[a] plaintiff must establish the court's jurisdiction with respect to each claim asserted." *Sunward Elecs., Inc. v. McDonald*, 362 F.3d 17, 24 (2d Cir. 2004).

(emphasis in original); *Vallarta v. United Airlines, Inc.*, 497 F. Supp. 3d 790, 802 (N.D. Cal. 2020) (declining "novel application" of pendent personal jurisdiction doctrine); *FCA US LLC Monostable Elec. Gearshift Litig.*, 2017 WL 11552971, at *5 (rejecting pendent personal jurisdiction to allow related claims by additional plaintiffs, noting the absence of "any court of appeals decision in any circuit that has extended the concept of pendent personal jurisdiction with such sweeping effect that can be squared with the constraints of the Due Process Clause."); *Tulsa Cancer Institute, PLLC v. Genentech Inc.*, 2016 WL 141859, at *4 (N.D. Okla. Jan. 12, 2016) (reversing prior holding permitting pendent personal jurisdiction over additional plaintiffs' claims).

In a March 2021 opinion rejecting application of pendent personal jurisdiction to additional plaintiffs, the district court for the Southern District of Florida stated that "*no* federal circuit court of appeals has adopted this pendent-*party* variety of personal jurisdiction." *Carter v. Ford Motor Co.*, 2021 WL 1165248, at *9 (S.D. Fla. Mar. 26, 2021). And indeed, a few months ago, the only Court of Appeals to consider this novel application of the pendent personal jurisdiction doctrine rejected it. *Canaday*, 9 F.4th at 401-02 (declining to find personal jurisdiction grounded in "relatedness" of claims between plaintiffs, and noting that "no federal statute or rule authorizes pendent claim or pendent party personal jurisdiction" and "[n]o such law exists—not in [] the supplemental jurisdiction statute, not in the Federal Rules of Civil Procedure"). Indeed, here, the NYAG not only seeks to piggyback on the jurisdictional predicate created by the claim a different plaintiff, in doing so, it seeks to expose Mr. Underwood to a category of remedies—financial damages under the GBL—that are not available under the FTC's "anchor" claim.

Absent the alleged jurisdictional "hook" of the FTC Act, this Court does not have personal jurisdiction over Mr. Underwood. There is no record evidence that Mr. Underwood himself transacted business in New York sufficient to establish specific jurisdiction under CPLR 302(a)(1). Nor can any acts by the corporation be imputed to Mr. Underwood to create specific jurisdiction under an "agency" theory, as the NYAG cannot satisfy its burden of demonstrating that Mr. Underwood was the "***primary actor***" behind Quincy's transactions in New York. Quincy is not an alter ego or agent of Mr. Underwood. Quincy has a marketing department with a marketing head; deposition testimony makes clear that Mr. Underwood was only one of a group of Quincy employees who approved edits to packaging, reviewed advertising, translated scientific research into marketing claims, and discussed, interpreted, and acted upon the results of the Madison Memory Study. There is therefore no dispute as to any material fact as to the exercise of specific personal jurisdiction over Mr. Underwood. *See In re Lyman Good Dietary Supplements Litig.*, 2018 U.S. Dist. LEXIS 131688, at *20 (S.D.N.Y. 2018) (finding no specific personal jurisdiction over claims against president/CEO of vitamin company where plaintiffs alleged only that the individual had "overall management responsibility" rather than "that they were the primary actors in the specific transactions giving rise to this action"); *Karabu Corp. v. Gitner*, 16 F. Supp. 2d 319 (S.D.N.Y. 1998) (Sotomayor, J.) (finding no specific personal jurisdiction over claims against individuals where complaint did not allege that individual was primary actor in relevant transaction, and noting that "control [for purposes of primary actor analysis] cannot be shown based merely upon a defendant's title or position within the corporation"). Allowing Mr. Underwood to be sued in New York based upon alleged corporate activity in New York that Mr. Underwood neither directed nor was the primary actor for would offend the Due Process clause of the Constitution. *See Walden v. Fiore,* 134 S. Ct. 1115, 1122-23 (2014) (holding that "[a] forum State's exercise of jurisdiction over an out-of-state intentional tortfeasor must be based on intentional conduct by the defendant that creates the necessary contacts with the forum" and that "the relationship must arise out of contacts that the 'defendant *himself* creates with the forum State") (emphasis in original).

Respectfully submitted,

COZEN O'CONNOR

/s/ Michael B. de Leeuw

BY: MICHAEL B. DE LEEUW

MEMO ENDORSED

Geoffrey W. Castello
Kelley Drye & Warren LLP
3 World Trade Center
175 Greenwich Street
New York, NY 10007
Tel: (973) 503-5922
Fax: (973) 503-5950
gcastello@kelleydrye.com

December 21, 2021

Via ECF
Hon. Louis L. Stanton, U.S.D.J.
United States District Court, Southern District of New York
500 Pearl Street
New York, NY 10007

Re: *FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.*
Case No. 1:17-cv-00124-LLS

Your Honor:

We represent defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc. and Quincy Bioscience Manufacturing, LLC (collectively, "Quincy") and respectfully request a pre-motion conference with respect to a motion for summary judgment pursuant to Federal Rule of Civil Procedure 56. The anticipated bases for Quincy's motion are set forth below.

I. The Challenged Claims are Clearly Substantiated Structure/Function Claims

After over six years of investigation and litigation, the record shows that there is no material disputed fact that Quincy has met the legal standard required to substantiate its claims. Summary judgment is therefore appropriate.

There is no dispute that Prevagen is a dietary supplement pursuant to the Dietary Supplement Health & Education Act of 1994 ("DSHEA") (Complaint ¶ 19), which permits "structure/function" claims without prior approval from the FDA. *See* 21 U.S.C. § 321(g)(1); 21 U.S.C. § 343(r)(6). Structure/function claims "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans," 21 U.S.C. § 343(r)(6), and include claims relating to "mild memory problems associated with aging." 65 Fed. Reg. 1000, 1000-01 (Jan. 6, 2000). As long as a dietary supplement is not marketed as a drug—i.e., does "not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of disease[,]" it is not regulated like a drug. 21 U.S.C. § 343(r)(6). Prevagen is not marketed as a drug.

In response to DSHEA, the FTC released guidance for supplement manufacturers: "Dietary Supplements: An Advertising Guide For Industry" ("Guidance"), Exhibit A. The Guidance was designed to advise industry that the substantiation standard for marketing claims for dietary supplements is "competent and reliable scientific evidence," defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area." Guidance at 3, 9. The Guidance makes clear that the FTC's standard is "flexible" with "no fixed formula for the number or type of studies required." *Id.* at 8-9. Randomized, controlled trials are *not* required. Indeed, other types of scientific evidence can substantiate dietary supplement marketing claims, including (among others): animal studies, *in vitro* studies, epidemiological evidence, and other human studies. *Id.* at 10. In contrast, the FDA *does* require randomized clinical trials for new *drug* applications. 21 C.F.R. § 314.126 (2002).

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Plaintiffs do not claim that Prevagen was marketed as a drug, but nevertheless attempt to hold Quincy to that higher drug substantiation standard—a standard that the Guidance makes clear is *not required* for dietary supplements. This novel approach would turn the dietary supplement industry on its head and should be rejected. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158-59 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.").

Plaintiffs allege that that following claims for Prevagen are false and misleading: (1) improves memory; (2) improves memory within 90 days; (3) reduces memory problems associated with aging; (4) provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking; and (5) is clinically shown to have such effects (the "Challenged Claims"). (Complaint ¶¶ 36-45.) These claims, which have been discontinued or substantially qualified as of the summer of 2020, are textbook structure/function claims, and are substantiated in accordance with the FTC's own standard.

The undisputed record shows that Quincy engaged a university research laboratory to conduct animal and *in vitro* studies, which showed the beneficial efficacy and safety of apoaequorin (the active ingredient in Prevagen). Quincy then moved to open label human studies that further substantiated the Challenged Claims. Following this positive evidence, Quincy conducted the Madison Memory Study—a double-blind, placebo controlled human clinical trial—that demonstrated that Prevagen improved memory and other cognitive function in its intended audience, namely healthy, older adults. In other words, even though a randomized clinical trial is not required, Quincy conducted one and its results substantiate the Challenged Claims. This Court has already determined based on Plaintiffs' admissions in the Complaint that "the complaint fails to show that reliance upon the subgroup data 'is likely to mislead consumers acting reasonably under the circumstances.'" ECF No. 45 at 11-12. Despite extensive discovery, nothing has changed since the Court arrived at that determination.

Five of Defendants' expert witnesses (in the relevant fields of internal medicine, nutrition, dietary supplement substantiation, epidemiology, and biostatistics) all confirm that the Madison Memory Study, and the earlier *in vitro* and animal studies, substantiate Prevagen's marketing claims in accordance with the Guidance. On the other hand, two of Plaintiffs' purported experts (in biostatistics and cognitive function) failed to even *consider* the standard as set forth in the Guidance, and ignored Quincy's animal and *in vitro* studies altogether. Instead, they nitpick aspects of the design and execution of the Madison Memory Study as if it were a clinical drug trial. None of Plaintiffs' experts even tested Prevagen, nor are they treating physicians, and Plaintiffs have proffered no extrinsic evidence about how consumers perceived the challenged marketing claims. In short, Plaintiffs merely urge their own judgment, having failed to adduce *any* evidence that the Madison Memory Study could *possibly* mislead consumers.

At most, Plaintiffs' third expert (a chemist)[1] disputes one *potential* "mechanism of action" for Prevagen but has not substantively opined on *several other* plausible "mechanisms of action" described by Quincy's experts. In any event, the law does not require a known "mechanism of action" for dietary supplement products (indeed, the FDA does not even require known "mechanisms of action" for *drug* approvals). The fact that Quincy has *several* plausible mechanisms only bolsters the extensive behavioral, clinical, and other substantiation showing Prevagen's beneficial effects.

There is also a vast body of scientific, epidemiologic and mechanistic evidence that Vitamin D, which has been an ingredient in Prevagen since 2016, can improve memory and/or cognitive function.

[1] Quincy's papers will make clear that Plaintiffs failed to proffer evidence from the relevant experts in this matter.

Plaintiffs' experts discount this evidence because they do not believe it satisfies the FDA's heightened substantiation standard for drugs. But again, these criticisms are misplaced and ignore the FTC's own standard as well as the regulatory regime under DSHEA.

Put simply, there can be no dispute that the Challenged Claims are supported by "competent and reliable scientific evidence" as defined in the Guidance. Other courts have rejected similar attempts by the FTC to require more substantiation than is required. *See, e.g., U.S. v. Bayer Corp.*, 2015 WL 5822595, at *3-4 (D.N.J. Sept. 24, 2015); *Basic Rsch., LLC v. FTC*, 2014 WL 12596497, at *10 (D. Utah Nov. 25, 2014) ("the FTC must do more than present an expert who simply disagrees with the scientific literature upon which [the defendant] relied. The FTC must present evidence that shows how [defendant's] evidence fails to meet" the definition of competent and reliable scientific evidence); *FTC v. Garden of Life, Inc.*, 516 F. App'x 852, 856 (11th Cir. 2013) (rejecting FTC's argument that defendant could be liable because the FTC's expert "disagrees with certain aspects of a study's 'trial design'" because doing so "would require this Court to read additional requirements" into the competent and reliable scientific evidence standard). The same result is warranted here.

II. Plaintiffs Lack the Ability to Pursue Injunctive Relief

The text of Section 13(b) of the FTC Act only contemplates prospective relief. *See* 15 U.S.C. § 53(b)(1) ("Whenever the Commission has reason to believe that any person, partnership, or corporation *is violating, or is about to violate*, any provision of law . . . .") (emphasis added). Courts have understood that language pursuant to its plain terms, holding that the FTC may not obtain injunctive relief where alleged violations are not ongoing or imminent. *FTC v. Qualcomm Inc.*, 969 F.3d 974, 1005 (9th Cir. 2020); *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 160 (3d Cir. 2019); *FTC v. Facebook, Inc.*, 2021 WL 2643627, at *19 (D.D.C. June 28, 2021). This past term, the Supreme Court interpreted the language the same way, noting that the statutory "provision focuses upon relief that is prospective, not retrospective." *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1348 (2021).

It is undisputed that the Challenged Claims are no longer being disseminated in the form challenged in the Complaint. In 2020, Defendants entered into a nationwide class action settlement in *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864 (S.D. Fla.), in which they agreed to add language that Prevagen's marketing claims are "based on a clinical study of subgroups of cognitively normal or mildly impaired individuals" i.e., healthy, older adults. All of Quincy's advertisements now contain this or a similar language, and therefore, even accepting Plaintiffs' allegations as true, there can be no dispute that Quincy is no longer "violating" or "about to violate" the FTC Act.

III. The NYAG's State Law Claims Fail for Additional Reasons

Because the Challenged Claims comply with DSHEA and the Guidance, the NYAG's GBL claims fail under the statute's safe harbor provisions (*see* N.Y. Gen. Bus. Law §§ 349(d), 350-d) and because they are preempted by DSHEA and the Food, Drug, and Cosmetic Act ("FDCA"). *See, e.g. In re PepsiCo, Inc. Bottled Water Mktg. and Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008). In addition, in light of the *Collins* class action settlement, the NYAG's claims for restitution must be enjoined or dismissed. *See In re Baldwin-United Corp.*, 770 F.2d 328, 337 (2d Cir. 1985); *California v. IntelliGender, LLC*, 771 F.3d 1169, 1172 (9th Cir. 2014) ("the appropriate State officials were notified, but they chose not to participate in the settlement approval process. The State cannot now obtain a duplicate recovery in the form of restitution on behalf of those individuals who are bound by the bargained for restitution in the CAFA class settlement."); *FTC v. AMREP Corp.*, 705 F. Supp. 119, 123 (S.D.N.Y. 1988).

December 21, 2021

Respectfully submitted,

/s/ Geoffrey W. Castello

Geoffrey W. Castello
Kelley Drye & Warren LLP
3 World Trade Center
175 Greenwich Street
New York, NJ 10007
Tel: (212) 808-7800
Fax: (212) 808-7897
gcastello@kelleydrye.com

Counsel for Defendants
Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc. and Quincy Bioscience Manufacturing, LLC

cc: All Counsel of Record (via Email)